

OCT 28 1999

K990410

APPENDIX 3.

Quest International, Inc., 1938 N.E. 148th Terrace, N. Miami, FL 33181
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510(k) SUMMARY

Applicant: Quest International, Inc.
1938 N.E. 148th Terrace
North Miami, FL 33181

Registration No. 1061839

Contact Person: Robert A. Cort, V.P. , Quality Assurance

Telephone: (305) 948-8788

Telefax: (305) 948-4876

Manufacturing Site: Same as above

Device: SeraQuest® EB VCA IgG

Device Name: Epstein-Barr virus serological reagents (21CFR § 866.3235)

Device Classification: Class I (general controls)

Description:

The SeraQuest EB VCA IgG test is a solid-phase enzyme immunoassay (EIA), which is performed in microwells, at room temperature, in three thirty minute incubations. It has been developed to detect IgG antibodies which are directed against Epstein-Barr virus capsid antigen, in human serum.

The Calibrators in the SeraQuest EB VCA IgG test set have been assigned Index values based on an in-house standard. Test results are reported as Index values.

Principle:

Diluted samples are incubated in wells coated with Epstein-Barr virus capsid antigen. Antibodies directed against Epstein-Barr virus capsid antigen (if present) are immobilized in the wells. Residual sample is eliminated by washing and draining, and conjugate (enzyme-labeled antibodies to human IgG) is added and incubated. If IgG antibodies to Epstein-Barr virus capsid antigen are present, the conjugate will be immobilized in the wells. Residual conjugate is eliminated by washing and draining, and the enzyme substrate is added and incubated. In the presence of the enzyme, the substrate is converted to a yellow end-product which is read photometrically at 405 nm.

Intended Use:

Intended Use: The EB VCA IgG test is intended for the qualitative and semi-quantitative detection of human IgG antibodies to Epstein-Barr viral capsid antigen, in human serum by enzyme

immunoassay, as an aid in differentiating active or recent Epstein-Barr virus infection from past infection. For manual use, or for use with the HyPrep System Plus. For In Vitro Diagnostic Use Only.

Predicate Device:

The SeraQuest EB VCA IgG test is substantially equivalent in intended use and performance, to the Gull Laboratories' EBV IgG ELISA test, Gull Laboratories, Inc., Salt Lake City, Utah.

Summary of technological characteristics:

<u>Characteristic</u>	<u>SeraQuest EB VCA IgG</u>	<u>Gull Laboratories ' EBV IgG ELISA</u>
Description:	Enzyme Immunoassay	Enzyme Immunoassay
Intended Use:	The detection of IgG antibodies against Epstein-Barr virus capsid antigen in human serum.	The detection of IgG antibodies against Epstein-Barr virus capsid antigen in human serum.
Solid Phase:	Plastic Microwell	Plastic Microwell
Antigen :	Recombinant p18	Purified gp 125
Number of Incubation Periods:	Three	Three
Sample Dilution:	1:50	1:21
Sample Incubation Duration:	30 minutes	30 minutes
Incubation Temperature:	Room temperature	37 °C.
Enzyme-labeled Conjugate:		
Antibody	Goat anti-human IgG	Goat anti-human IgG
Enzyme	Alkaline phosphatase	Alkaline phosphatase
Conjugate Volume:	100 µl	100 µl
Conjugate Incubation Duration:	30 minutes	30 minutes
Substrate:	p-Nitrophenyl phosphate	p-Nitrophenyl phosphate

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Substrate Volume:	100 µl	100 µl
Substrate Incubation Duration:	30 minutes	30 minutes
Stop Reagent:	0.5 M Trisodium phosphate	1.5 N Sodium hydroxide
Stop Reagent Volume:	100 µl	100 µl
Readout:	Spectrophotometric 405 nm	Spectrophotometric 405 nm

Summary of Clinical Testing:

Of the 157 specimens tested, 130 were positive, and 9 were negative in both the SeraQuest and Gull Laboratories' tests (please see Table C-3). Of the 18 remaining specimens, 1 specimen which was negative by the Gull test, was positive by the SeraQuest test, and 11 specimens which were positive by the Gull test, were negative by the SeraQuest test. Six specimens gave equivocal results in one or both of the tests being compared. Please see Table 1 below.

TABLE 1.

RESULTS OF SeraQuest EB VCA IgG ASSAYS, AND GULL VCA IgG ASSAYS, OF 157 SERUM SPECIMENS. THESE TESTS WERE PERFORMED IN-HOUSE AT QUEST INTERNATIONAL, INC., MIAMI, FL.

GULL VCA IgG	SeraQuest EB VCA IgG				%	95 % CI [√]
	Positive	Equivocal	Negative			
Positive	130	2	11	Relative sensitivity*	92.2	87.8 to 96.6
Equivocal	2	1	0			
Negative	1	1	9	Relative specificity*	90.0	71.4 to 100
				Overall agreement*	92.1	87.7 to 96.4

* Excluding equivocal results.

√ Calculated by the normal method.

Reference: Gardner, M.J. and Altman, D.G., Confidence Intervals Rather Than Hypothesis Testing. Brit. Med. J., 292: 746-750, 1986.



DEPARTMENT OF HEALTH & HUMAN SERVICES

OCT 28 1999

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

Mr. Robert A. Cort
Vice President, Quality Assurance
Quest International, Inc.
1938 N.E. 148th Terrace
North Miami, Florida 33181

Re: K990410
Trade Name: SeraQuest EB VCA IgG
Regulatory Class: I
Product Code: LSE
Dated: August 12, 1999
Received: September 8, 1999

Dear Mr. Cort:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

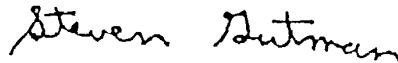
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Under the Clinical Laboratory Improvement Amendments of 1988 (CLIA-88), this device may require a CLIA complexity categorization. To determine if it does, you should contact the Centers for Disease Control and Prevention (CDC) at (770)488-7655.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4588. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll free number (800) 638-2041 or at (301) 443-6597 or at its internet address "<http://www.fda.gov/cdrh/dsmamain.html>"

Sincerely yours,

A handwritten signature in black ink that reads "Steven Gutman". The signature is written in a cursive, slightly slanted style.

Steven I. Gutman, M.D., M.B.A.
Director
Division of Clinical Laboratory Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

APPENDIX 6

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510(k) Number (if known): _____

Device Name: SeraQuest EB VCA IgG

Indications For Use:

1. For in vitro diagnostic use only.
2. For the qualitative and semi-quantitative detection of IgG antibodies to Epstein-Barr viral capsid antigen (VCA) in human serum by enzyme immunoassay.
3. For use as an aid in differentiating active or recent infection, from past infection.
4. For manual use, or for use with the HyPrep System Plus semi-automated fluid handler.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Woody Dubois
(Division Sign-off)
Division of Clinical Laboratory Devices
510(k) Number K990410

Prescription Use X
(Per 21 CFR 801.109)

OR

Over-The-Counter Use _____

(Optional Format 1-2-96)